AUG 1 2013

K130033

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Elizabeth Wray
Date prepared	June 21, 2013
Name of device	
Trade or proprietary name	ToggleLoc™ System
Common or usual name	Soft tissue fixation devices
Classification name	- fastener, fixation, nondegradable, soft tissue - staple, fixation, bone
Classification panel	Orthopedic
Regulation	888.3040 and 888.3030
Product Code(s)	MBI and JDR
Legally marketed device(s) to which equivalence is claimed	K083070 ToggleLoc™ System (Biomet) K102982 EndoButton CL (Smith & Nephew) K112990 TightRope RT (Arthrex)
Reason for 510(k) submission	Additional metallic ToggleLoc™ buttons and ZipLoop™ constructs. Addition of magnetic resonance (MR) compatibility language to product labeling.
Device description	This submission is for the ToggleLoc™ System in which a series of titanium and stainless steel ToggleLoc devices are being included. These items include the ToggleLoc™ XTender, ToggleLoc™ XL with ZipLoop™ Technology, ToggleLoc™ with ZipLoop™ Inline, expanded offering of components of the previously cleared ToggleLoc™ with ZipLoop™ System (K083070), and implants previously cleared in K083070 being included in this submission to add MRI language.
Intended use of the device	Soft tissue fixation

Indications for use	The ToggleLoc™ System devices, except the ToggleLoc XTender and ToggleLoc XL devices, are intended for soft tissue to bone fixation for the following indications: **Shoulder:** Bankart lesion repair, SLAP lesion repairs Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps Tenodesis **Foot and Ankle:** Medial/lateral repair and reconstruction, Mid- and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair, Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (**only for ToggleLoc™ with ZipTight™**) **Elbow:** Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment **Knee:** ACL/PCL repair / reconstruction, ACL/PCL patellar bone-tendon-bone grafts, Double-Tunnel ACL reconstruction, Extracapsular repair: MCL, LCL, and posterior oblique ligament, Illiotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure **Hand and Wrist:** Collateral ligament repair, Scapholunate ligament reconstruction, Tendon transfers in phalanx, Volar plate reconstruction **Hip:** Acetabular labral repair The ToggleLoc XTender and ToggleLoc XL devices are used for fixation of tendons and ligaments in cases of unanticipated intraoperative complications such as cortical breaching during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction. The ToggleLoc™ XTender is for use in conjunction with a titanium alloy ToggleLoc™ device, excluding the ToggleLoc™ XL devices.
Summary of the Technologies	
The ToggleLoc™ System is made up of various combinations of components, including: ToggleLoc buttons, ZipTight construct and buttons, Continuous Loops, and ZipLoop™ Technology. The technological characteristics of the ToggleLoc™ System are the same as those of predicate	

devices (K083070) in terms of design, material, and principles of operation with the exception of slight modifications as described in this 510(k). The ToggleLoc™ System utilizes the identical manufacturing processes as the predicates (K083070).

Non-clinical testing was conducted to demonstrate that the differences did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components. All testing met or exceeded the established acceptance criteria. This information is detailed below in the Performance (Non-clinical) section.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS

Performance Test Summary-New Device

The following tests were performed on the ToggleLoc™ System:

Static Load Testing: ToggleLoc™ System Line Extensions
Cyclic Load Testing: ToggleLoc™ System Line Extensions
MR Evaluation/Simulations

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: N/A

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

No clinical testing was necessary for a determination of substantial equivalence.

The results of mechanical testing indicated the devices performed mechanically equivalent to marketed devices and did not raise any new safety and efficacy issues. The results of the MR evaluation indicated that the devices are MR Conditional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corporation
% Ms. Elizabeth Wray
Global Regulatory Project Manager
56 East Bell Drive
Warsaw, Indiana 46581

August 1, 2013

Re: K130033
Trade/Device Name: Toggleloc™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: June 28, 2013
Received: July 3, 2013

Dear Ms. Wray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130033

Device Name: Toggleloc™ System

Indications For Use:

The ToggleLoc™ System devices, except the ToggleLoc XTender and ToggleLoc XL devices, are intended for soft tissue to bone fixation for the following indications:

Shoulder
Bankart lesion repair
SLAP lesion repairs
Acromio-clavicular repair
Capsular shift/capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps Tenodesis

Foot and Ankle
Medial/lateral repair and reconstruction
Mid- and forefoot repair
Hallux valgus reconstruction
Metatarsal ligament/tendon repair or reconstruction
Achilles tendon repair
Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (**only for ToggleLoc™ with ZipTight™**)

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

510(k) Number (if known): K130033

Device Name: Toggleloc™ System

Indications For Use:

Elbow
Ulnar or radial collateral ligament reconstruction
Lateral epicondylitis repair
Biceps tendon reattachment

Knee
ACL/PCL repair / reconstruction
ACL/PCL patellar bone-tendon-bone grafts
Double-Tunnel ACL reconstruction
Extracapsular repair: MCL, LCL, and posterior oblique ligament
Iliotibial band tenodesis
Patellar tendon repair
VMO advancement
Joint capsule closure

Hand and Wrist
Collateral ligament repair
Scapholunate ligament reconstruction
Tendon transfers in phalanx
Volar plate reconstruction

Hip
Acetabular labral repair

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

510(k) Number (if known):

K130033

Device Name: Toggleloc™ System

Indications For Use:

The ToggleLoc XTender device is used for fixation of tendons and ligaments in cases of unanticipated intraoperative complications such as cortical breaching during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction. The ToggleLoc™ XTender is for use in conjunction with a titanium alloy ToggleLoc™ device, excluding the ToggleLoc™ XL devices.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices